Single Emergent Use of a Test Article
(investigational drug, biological product, or medical device)

The investigator (licensed physician) treating the patient **must notify** their local Trinity Health Michigan IRB **prior to** the emergency use of a test article **by submitting Pages 1 – 2 of this form** and **within 5 working days** after use of the test article **submit Page 3** (Follow-up Report) for IRB review/determination.
If it is not feasible to notify the IRB prior to use of a test article due to the life-threatening situation **you must submit the entire form within 5 working days** after the use.

The investigator must **determine the following criteria is met** for the use of a test article:

1. Patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
2. Potential patient benefit justifies the potential risks of the use
3. The patient's condition requires immediate intervention before review at a convened meeting of the IRB is possible to avoid major irreversible morbidity or death.

Test Article Information

NAME of Drug, Biologic, or Device	Manufacturer	IND/IDE#
		Provide a copy of the FDA letter granting use with this report.
Date IRB Chair Permission Obtained	**Date Test Article Used or Will Be Used**	**Dosage**

Describe the Indication/Patient's Condition that Required Emergency Use of the Test Article

Informed Consent

Was the patient or Legally Authorized Representative (LAR) Informed Consent obtained?

Yes – Investigator must provide a summary of the consent process in the Follow-up Report section within 5 days.

No – it was not feasible to obtain informed consent from the patient/LAR prior to use of the test article. The investigator and an independent physician **NOT** involved in the patient's treatment certifies by signing this form that the following **Request For Waiver Of Informed Consent met all conditions:**

1) The patient is confronted with a life-threatening situation necessitating an immediate use of the test article
2) The patient is unable to provide effective consent
3) There is insufficient time in which to obtain consent from the patient's legally authorized representative
4) There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of treating the patient's condition

Single Emergent Use of a Test Article

Investigator Certification/Signature

By signing I acknowledge/certify the following to be true:

- ✓ Criteria is met for the use of a test article.
- ✓ **If emergency use is a drug/biologic** FDA **prior** approval was obtained and the requested use will not interfere with the initiation, conduct, or completion of a clinical investigation supporting marketing approval/potential development; ***or***
- ✓ **If emergency use is a device**, there is no time to use existing procedures to obtain FDA approval due to the immediate patient need and the CMO/IO signature was obtained (included on this form) for institutional clearance.
- ✓ The outcome of this emergency use may not be included in any report of research activity, except for case reports; and
- ✓ The patient may not be considered a research subject and any data generated may not be claimed as research.
- ✓ If a Request For Waiver Of Informed Consent was sought all conditions existed, and the requirements for an Exception from Informed Consent are met.
- ✓ Subsequent use of the test article in the same or different patient requires submission of an IRB application for full board review.

Investigator Printed Name		Investigator Signature		Date	

Independent Assessment by Uninvolved Physician Signature

By signing I confirm I did Not participate in the clinical treatment of the patient and certify:

- ✓ The patient is in a life-threatening situation for which no acceptable treatment is available.
- ✓ There is insufficient time to obtain approval of the full board IRB for use of the test article.
- ✓ The outcome of this emergency use may not be included in any report of research activity, except for case reports; ***and***
- ✓ The patient may not be considered a research subject and any data generated may not be claimed as research.

Physician Uninvolved Printed Name		Physician Uninvolved Signature		Date	

Waiver Of Informed Consent Independent Physician Signature

By signing I certify:

- ✓ The Request For Waiver Of Informed Consent met all conditions/requirements for an Exception from Informed consent.

Independent Physician Printed Name		Independent Physician Signature		Date	

IRB Chair/Designee Signature

By signing I certify:

- ✓ I reviewed documents for the emergency use and provide an acknowledgement of concurrence that the conditions/criteria is met for the use of the test article.

Chair or Designee Printed Name		Chair or Designee Signature		Date	

Chief Medical Officer (CMO)/Institutional Official (IO) Institutional Acknowledgment of Awareness (Only required for use of a device)

CMO/IO Printed Name		CMO/IO Signature		Date	

Single Emergent Use of a Test Article

After the use of a test article **Complete the Follow-up Report Section** and **submit within 5 days After Emergency Use of a Test Article.**

NAME of Drug, Biologic, or Device	Investigator Name	Date Test Article Used

Follow-up Report

Description of Consent Process
Include an unsigned copy of the consent document provided to the patient

Results of the Emergency
Include Adverse Events

Evaluation of Similar need for the Emergency Use of this Test Article:
Note: Any further use of the investigational drug or biologic at Trinity Health Michigan is subject to IRB Review

IRB Review/Determination

The report will be reviewed by the IRB at a convened meeting. IRB review is not merely confirmation of the emergency use but is an assessment of the circumstances, the appropriateness of the emergency waiver, and the consent process employed. Following the meeting, the investigator will receive a final acknowledgment in the form of a letter to be maintained in their records for audit purposes.

IRB Chair/Designee Confirmation

I confirm at a convened meeting the IRB performed an assessment of the situation, the appropriateness of the Emergency Waiver and the consent process employed.

Chair or Designee Printed Name		Chair or Designee Signature		Date	